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CENTER FOR DISEASE CONTROL

Morbidity and Mortality

WEEKLY REPORT

For Week Ending March 6, 1971

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE / PUBLIC HEALTH SERVICE / HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

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EPIDEMIOLOGIC NOTES AND REPORTS

NOSOCOMIAL BACTEREMIAS ASSOCIATED WITH INTRAVENOUS FLUID THERAPY – USA

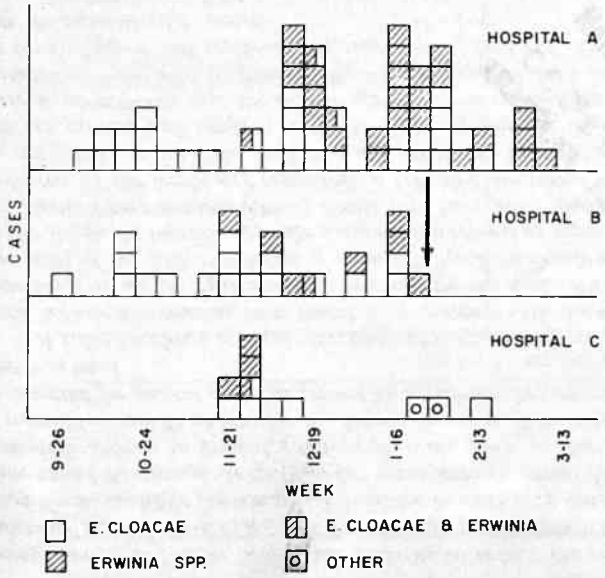
Between October 1970 and March 1, 1971, eight United States Hospitals in seven states experienced 150 bacteremias caused by *Enterobacter cloacae* or Gram-negative organisms of the Erwinia group. There were nine deaths; all were associated with intravenous (IV) fluid therapy. The Enterobacter bacteremias in all hospitals were substantially increased as compared to previous time periods. Four hospitals which isolated and identified Erwinia had not previously encountered infections with these organisms. In-depth epidemiologic investigations were performed in three of the hospitals (Figure 1).

All eight hospitals utilize fluids and systems manufactured by Abbott Laboratories, which produces approximately 45 percent of all IV fluids sold within the United States. In approximately 30 cases, the same organisms were isolated from blood cultures and contaminated in-use IV fluids. In hospital B (see arrow, Figure 1) no further cases were observed after discontinuance of Abbott products.

Enterobacter cloacae is occasionally encountered as an agent of bacteremia in American hospitals. However, unless fully speciated, this organism will not be identified. Erwinia, most well known as a plant pathogen, has only very rarely been isolated from human infection *(1)*. Erwinia may be confused with members of the Klebsiella-Enterobacter group, and a rather detailed series of biochemical tests, with special emphasis on decarboxylase reactions, are needed to reliably differentiate the organisms.

Figure 1

IV-ASSOCIATED SEPTICEMIAS, BY WEEK OF ONSET, 1970-1971



These septicemias were consistantly characterized by intermittent high fever, although shock was infrequent. Young individuals or other patients without predisposing host factors were frequently afflicted. The great majority of cases simultaneously manifested extensive phlebitis at the site of infusion which occurred even when polyethylene catheters had been in place for only brief periods, and also occurred where only scalp vein needles were used. Discontinuance of IV therapy has resulted in dramatic clinical improvement; if such therapy is continued, however, antimicrobials have frequently been without apparent effect on the course of the infection.

Studies of IV systems by CDC have shown a minimum of 6 percent prevalence of contamination within the tubing or bottles after the system has been in use. A significantly greater risk of contamination was noted in all systems where administration apparatus remained unchanged for greater than 48 hours. The studies also revealed that routine once-daily complete change of all IV administration apparatus, especially at the time of replacement of infusion devices (polyethylene catheters, needles, etc.) can greatly decrease the hazard of extrinsic contamination by preventing introduced organisms from propagating to dangerous levels.

Bacterial contamination of the outer surface of the insert discs (synthetic cap liner) of unopened Abbott bottles has recently been demonstrated by CDC, which ranges from 0 to 52 percent among sampled lots. Bacillis species, *S. epidermidis, Pseudomonas maltophillia* and yeasts have been most frequently isolated, however, *E. cloacae* or Erwinia species have been isolated from 12 of 212 caps tested. Between April and September 1970, Abbott Laboratories partially converted to a new type of cap liner.

Direct sampling of fluids from intact non-manipulated bottles by CDC has been negative, but transfer of organisms from contaminated caps to the fluid has been effected approximately 25 percent of the time by sequentially striking the cap several times, unscrewing and replacing it, and then hanging the bottle inverted for 24 to 48 hours. Transfer of organisms from contaminated caps to the fluid of bottles, where the cap has not been manipulated, has not been demonstrated, but is currently under further investigation. Once inoculated into commercial dextrose containing solutions, organisms of the Klebsiella-enterobacter group are capable of proliferating at room temperature, whereas other tested members of the Enterobacteriacae or Staphylococci either fail to grow or die.

(Reported by the Food and Drug Administration and the Center for Disease Control.)

Reference:

1. von Graevenitz A: Erwinia species isolates. Ann NY Acad Sci 174(2): 436-443, 1970.

Editorial Comment:

The following press release was issued March 13, 1971:

The Commissioner of Food and Drugs, Dr. Charles C. Edwards, and the Director of the Center for Disease Control, Dr. David J. Sencer, today announced that special precautions must be taken in hospitals,

nursing homes, and other health care facilities to reduce the risk of septicemia from the use of Abbott Laboratories intravenous (IV) infusion products. While contamination resulting in septicemia can occur in the use of infusion products from any manufacturer, recent Abbott production appears to present a unique problem. These products will be replaced as rapidly as possible by Abbott, however, these solutions are essential for patient care and cannot be withdrawn before replacement is in hand.

A rising incidence of septicemia caused by organisms rarely associated with septicemia has been found in connection with the use of intravenous fluids in eight hospitals surveyed by the CDC. All eight were users of the Abbott infusion system. CDC has been closely examing the fluids, the infusion apparatus, and clinical reports of septicemia. The plastic liners in some Abbott bottle caps have been found contaminated by the implicated organisms. A tentative conclusion is that the organisms can enter the fluid from the plastic cap liners when the caps are opened and replaced while the bottle is held for later use. There is no evidence that the closure system allows or contributes to contamination before it is opened. It has been shown that when the cap has been removed and replaced that migration of bacterial organisms from the cap lining may occur.

The bottles of fluid known to be involved have been manufactured from February 1970 and they bear codes beginning with 842 through 855.

Teams of experts from CDC, FDA, and Abbott Labs are reviewing all aspects of the problem. This review will be completed within a few days and it is expected that a resolution will be developed rapidly.

Meanwhile, with cooperation of the American Hospital Association, hospitals and other users of these solutions are being advised of special procedures to reduce the contamination hazard to a minimum. These procedures include: opening the containers at the point of use only; not replacing the cap; and using the contents of the containers immediately upon opening. Hospitals also are being advised to change IV apparatus at least every 24 hours. The CDC studies have demonstrated that any brand of IV apparatus is more likely to cause infection if left in place longer.

CDC and FDA conclude that the joint actions being taken are reasonable and necessary in the interest of patient care and to prevent a disruption in the availability of these essential drugs.

On the basis of the studies conducted thus far, several additional specific measures which might minimize the risk of contamination from Abbott products are recommended:

1. At the first suspicion of clinical septicemia or fever which might be associated with contaminated intravenous fluid, all existant IV apparatus should be removed and microbiologically sampled; if continued IV therapy is necessary, it should be reinitiated with entirely new equipment and solutions.
2. Bottle caps should not be struck or otherwise traumatized to effect removal. If a cap is not easily removed, the bottle should be discarded.
3. A cap should never be replaced after the bottle has been opened.

Medical queries should be directed to the CDC, Area Code 404/ Day: 633-3311, Ext. 3684; Nights and weekends: 633-2176. Compliance queries should be directed to FDA, Area Code 301/ Day: 443-1717; Nights and weekends: 933-7377.